Online Controlled Substances Summit

Public Session

Thursday, July 25, 2024

11 am to 2 pm (Eastern), Zoom Virtual Platform

Speaker Biographies

Opening Remarks

Robert M. Califf, MD, MACC

Commissioner of Food and Drugs, U.S. Food and Drug Administration

Dr. Robert M. Califf was confirmed earlier this year as the 25th Commissioner of Food and Drugs. As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products. Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care. This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco.

Speakers

Murray Aitken, MBA, MCom

Senior Vice President

IQVIA

Murray Aitken is a senior vice president of IQVIA, Executive Director of the IQVIA Institute for Human Data Science, and a Visiting Professor in Practice at the London School of Economics and Political Science. The IQVIA Institute undertakes independent research, drawing upon the resources of IQVIA, and focuses on the role of medicines in patient care, the disruptive impact of technology, productivity in research and development, and the value of information in improving decision-making. He directs the Institute's activities and co-authors reports, while also engaging externally with a broad range of healthcare decision-makers in the public and private sectors. Reports by the Institute are widely cited by policy-makers, referenced in peer-reviewed research, and covered by the media. He holds an MBA degree with distinction from Harvard University and a Master of Commerce degree from the University of Auckland, New Zealand.

Megan Jones Bell, PsyD
Director of Consumer and Mental Health
Google

Dr. Megan Jones Bell, director of Consumer and Mental Health at Google, is a psychologist and health leader working at the intersection of health and technology. She has dedicated her career to improving mental and physical health for all with a focus on scaling access to evidence-based information and interventions using technology. Dr. Jones Bell has been a longtime advocate for mental health and has brought her human-centered approach into her work in academia, nonprofits, and the private sector. She brings this dedication to her work at Google where her team of health and strategy professionals provide guidance for the development of Google's consumer health products including Fitbit, Pixel, YouTube, and other surfaces. Dr. Jones Bell also founded and leads the company-wide Mental Health Center of Excellence which guides Google's efforts to promote and protect the mental health of billions of people and enable access to and quality of mental healthcare through strategic partnerships. She was chief strategy and science officer at Headspace and helped guide Headspace through its transformation from a meditation app into a comprehensive digital mental health platform, Headspace Health. Megan founded one of the first digital mental health companies, Lantern, where she pioneered blended mental health interventions leveraging software and coaching. Megan was an assistant professor in Psychiatry and Behavioral Sciences at Stanford University School of Medicine. She serves on several boards, advises organizations dedicated to mental health and well-being and is a Fellow of the Aspen Institute Health Innovators Fellowship and a member of the Aspen Global Leadership Network. Megan earned her BA, graduating cum laude, from University of California, San Diego. She received her MS and PsyD from PGSP-Stanford University, and completed fellowships at Yale University and Stanford University School of Medicine.

Dan Burke
Chief, Investigative Services Division
Office of Criminal Investigations
U.S. Food and Drug Administration

Special Agent Dan Burke started his federal law enforcement career with the IRS-Criminal Investigation Division in 1995 in Fargo, ND and later McAllen, TX. In 1997, he moved to the U.S. Customs Service in Denver, CO where he primarily investigated on-line child pornography, drug and financial investigations. In 2002, he was promoted to Supervisory Special Agent for U.S. Customs/Homeland Security Investigations in San Diego, CA where he managed the HIDTA Financial Task Force. Dan joined FDA-OCI in 2005 in the Kansas City Field Office and transferred to the Denver Domicile in 2008. In 2012, Dan was promoted to Senior Operations Manager for cybercrime investigations and later Senior Advisor to the Assistant Commissioner. In 2019, he was promoted to Chief of the Investigative Services Division with oversight over OCI's Cybercrime, Digital Forensics and Technical Surveillance Units as well as OCI's Training, Firearms, and Information Disclosure Units.

Dan has also been active with OCI's international expansion, liaison, and training initiatives. He currently serves as Chairman of the Permanent Forum on International Pharmaceutical Crime (pfipc.org). Over his career, Dan completed several successful cybercrime investigations spanning the globe and led the development of OCI's cyber operations. He has been part of OCl's digital forensics cadre since 2007 and has provided a wide variety of cyber-related training to domestic and foreign law enforcement partners. Dan holds several certifications in digital forensics and master's degrees in Cybersecurity from Missouri State University and Criminal Justice Administration from the University of Colorado-Denver, where he has served as part of their adjunct faculty for the last 14 years.

Kaitlyn Brown, PharmD, DABAT
Clinical Managing Director
America's Poison Centers

Dr. Brown is the Clinical Managing Director for America's Poison Centers. In this role, she leads the National Poison Data System's surveillance and data analysis work including relationships with public health and industry partners. Dr. Brown previously worked for many years providing on-the-ground clinical toxicology and regional poison center leadership.

Sean Ferns
Chief, Community Outreach & Prevention Support
Office of Public Affairs, Drug Enforcement Administration

Sean Fearns serves as the Chief of Community Outreach and Prevention Support for DEA since 2015. In this capacity Sean is responsible for growing and guiding a diverse and creative staff to develop and implement strategic national drug education efforts and partnerships with other organizations at the federal, state, and local levels. These partnerships and initiatives help educate the public on the current drug threats facing the country, support the DEA field offices, implement DEA's Operation Engage, communicate key Administration drug use prevention messages, and help reduce the demand for illegal drugs. Sean joined DEA in 1998 and previously served as the first Director of the DEA Museum from 2000 to 2015.

Angela Hoth, PharmD, MPH
Consultant
Reagan-Udall Foundation for the Food and Drug Administration

Angie Hoth is currently a research consultant with the Reagan-Udall Foundation for the Food and Drug Administration, working on projects in the Substance Use Disorder and Regulatory Science Accelerator programs. Dr. Hoth has over 30 years of experience as a clinical pharmacy specialist, working in primary care, geriatrics, mental health, and HIV prevention. Her passion is in the implementation and evaluation of novel clinical collaborative services. She was the program lead for a five-year CDC-funded PS18-1802 Component B Demonstration Project: Tele-Medical Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State which established the statewide Iowa TelePrEP service. Prior to that she was employed by the Iowa City VA Medical Center for fifteen years and worked on a wide variety of projects in health services research, program evaluation, and in the tech sector. Dr. Hoth received her B.S. Pharmacy degree at the University of Iowa College of Pharmacy, her Pharm.D. at the University of Texas Health Science Center in San Antonio, TX, completed a specialty residency in primary care and geriatrics at the Audie L. Murphy VA in San Antonio, TX, and received her MPH at the University of California, Berkeley. She began her pharmacy career as an assistant professor at the University of Kentucky College of Pharmacy.

Coreen Johnson
Senior Project Coordinator, Arapahoe County Chapter Lead & Program Coordinator
Young People in Recovery

Coreen Johnson has been with Young People in Recovery for 7 years and currently serves as the Senior Project Coordinator, Arapahoe Chapter Lead, and Program Coordinator. In her primary role, she manages program data and ensures the effective capturing of participants' recovery capital index scores. Coreen believes in the power of the recovery movement and align with the vision statement of YPR. "YPR envisions a world where every young person has access to the resources they need to thrive in recovery from drugs and alcohol. Her extensive experience presenting and facilitating groups started over twelve years ago while teaching in Denver Public Schools. In the last seven years, her world has been filled with implementing, collaborating on, and hosting groups through YPR's Life Skills classes, All Recovery Meetings, Workshops, and internal educational forums. She has provided countless free training on harm reduction and the use of life-saving Naloxone. And has also boldly advocated for legislation directly impacting the recovery community in front of the state house and senate numerous times to help push for Colorado to be a more recovery-ready place to live. In celebration of Coreen's exceptional advocacy and leadership achievements, she was the inaugural recipient of Young People in Recovery's "Coreen Braden Johnson- Distinguished Service Award," an award named in her honor. She is a firm believer in empathetically encouraging individuals to open their minds to new perspectives to create meaningful change in their own lives and the lives of their fellow community members.

Tim K. Mackey, MAS, PhD
Professor
University of California, San Diego

Tim Ken Mackey is a Professor of Global Health in the Global Health Program at UC San Diego, the Director of the Global Health Policy and Data Institute, and the Editor-in-Chief of JMIR Infodemiology. He is also the CEO and co-founder of the data science and research services company S-3 Research. He holds a BA in Political Science-International Relations, a Masters Degree in Health Policy & Law and also earned his PhD in Global Public Health from the joint doctoral program at UC San Diego - San Diego State University. Prof. Mackey's work focuses on an array of multidisciplinary topics, including examining various online illicit markets for access to controlled substances, prescription drugs, tobacco products, cannabis, firearms, and wildlife trafficking. His methodologies encompass data science, big data, machine learning, and policy studies to address critical public health challenges including on topics to advance health equity. He also has extensive professional experience including over 10 years working in the private sector and acting as a consultant for the World Health Organization, the US Department of State and others.

Justin Macy, PharmD, JD
Director of Innovation
National Association of Boards of Pharmacy

Justin specializes in the intersection of law, technology, and healthcare with a focus on pharmacy practice and drug regulation. Recently, Justin helped lead NABP's DSCSA efforts to support regulators, dispensers, and other trading partners by providing tools and education which enable implementation of DSCSA's interoperability milestone (Pulse by NABP). Historically, Justin has worked closely with NABP's Digital Health team. Prior to joining NABP, Justin was a specialist in Amazon's Consumer Legal Department and Associate Director of Innovation for a tech start-up.

Amanda Plisner, JD
Senior Manager, Proactive Trust and Safety Operations
Snap, Inc.

Amanda Plisner is a Senior Manager on Snap's Trust and Safety team, where she is responsible for the operational component of the company's proactive safety initiatives. Her scope includes safety strategy, proactive detection, investigations, and third-party intelligence and research. Prior to joining Snap, Amanda spent her career working in government, most recently as a Deputy Attorney General at the California Department of Justice, and the Department's Statewide Human Trafficking Coordinator. Throughout her career as a prosecutor, Amanda worked with U.S. local, state and federal agencies to investigate and prosecute a broad variety of criminal cases, with the majority of her time spent prosecuting drug sales and human trafficking cases while serving on multi-agency task forces. Amanda has also coordinated several of California's key anti-human trafficking initiatives, trained

law enforcement officers in the U.S. and abroad on the effective investigation of criminal cases, and advised California state agencies on the development and implementation of healthcare, education, and social programs.

Marta Sokolowska, PhD
Deputy Center Director for Substance Use and Behavioral Health
Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration

Marta Sokolowska, Ph.D., is the Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER). She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs. Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use. Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Erin Stack, M.S.
Director of Research and Evaluation
Comagine Health

Erin Stack, M.S., is the Director of Research and Evaluation at Comagine Health. Ms. Stack has 15 years of experience supporting and leading research and evaluation projects and has expertise in community-based research and participatory, empowerment, and culturally responsive evaluation approaches. Ms. Stack is trained as a community psychologist and her research over the years has focus broadly on studying interventions and programs aimed to promote community health, equity, and safety. She is currently a co-investigator on a NIDA-funded project exploring the impact of peer-delivered contingency management on harm reduction, treatment, and recovery outcomes among people who use stimulants. She also serves as the evaluation lead for two CDC-funded projects: 1) Oregon's Overdose Data To Action project, which aims to implement a strategic overdose prevention and response plan using surveillance data and community-driven

interventions, and 2) the Umatilla County Outreach, Prevention, Engagement (U-COPE) project, which aims to improve access to services for people who use drugs through peer-delivered services and enhanced community collaboration.

S. Leigh Verbois, Ph.D.
Director, Office of Drug Security, Integrity and Response
Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration

S. Leigh Verbois, Ph.D. serves as Director of the Office of Drug Security, Integrity and Response in CDER's Office of Compliance where she provides strategic leadership of pharmaceutical supply chain compliance and enforcement programs for the U.S. Food and Drug Administration. Dr. Verbois previously served as the Director of the Office of Global Operations in the Office of Global Policy and Strategy and Acting Assistant Commissioner for International Programs, where she led operations, policy and engagement of FDA's diplomatic missions to protect and promote public health. She also led FDA's efforts in the People's Republic of China as the FDA Country Director. Before posting to China, she directed FDA regulatory engagement with countries in the Asia-Pacific, Middle East, Africa and Canada. Dr. Verbois began her FDA career as a reviewer in CDER's Office of New Drugs. Dr. Verbois received her undergraduate degree from Tulane University, her Ph.D. in Pharmaceutical Sciences from the College of Pharmacy at the University of Kentucky and completed her postdoctoral training at the National Institutes of Health.

Ernest Voyard, JD
Director of Public Policy
Meta

Ernest Voyard serves as a Director of Public Policy at Meta, where he focuses on policy issues relevant to Instagram and Threads. Prior to Meta, Ernest was a Director of Regulatory Policy and Intelligence at Johnson and Johnson. There he focused on policy issues related to the development and promotion of drugs and biologic products. Ernest spent most of his early professional years as Regulatory Counsel at the US Food and Drug Administration (FDA).

Chris Wilks, PhD, MPA
Senior Consultant
Health Management Associate

Chris Wilks is a senior consultant for Health Management Associate. She manages long-term research projects and works closely with clients and project managers to design and execute projects to meet client objectives. She provides content expertise on population health, behavioral health disorders, chronic disease prevention, strategic planning, and qualitative research methods. Before joining HMA, Dr. Wilks managed almost $80 million in community-based grants to provide homelessness prevention services and recovery supports for SUD to 20,000 individuals and families. She conducted and published original quantitative and qualitative research projects and service evaluations on behalf of state and local governments and nonprofit foundations. Her research focuses on using group and individual interviews of service recipients and staff to inform effective changes in organizational and governmental health-related activities. Dr. Wilks earned her doctorate in public health from Ohio State University, a master's degree in public administration from New York University, and a bachelor's degree in anthropology from Yale University.

Meeting Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the Food and Drug Administration

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her juris doctorate *magna cum laude* from Georgetown University Law Center. She is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.